DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 17, 2015

Atricure, Inc.
Brittany Lowe
Regulatory Affairs
6217 Centre Park Drive
West Chester, Ohio 45069

Re: K150996
Trade/Device Name: Atriclip LAA Exclusion System with Preloaded Gillinov-cosgrove Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: June 1, 2015
Received: June 2, 2015

Dear Ms. Lowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150996

Device Name
Atriclip Laa Exclusion System With Preloaded Gillinov-cosgrove Clip

Indications for Use *(Describe)*
The AtriClip™ LAA Exclusion System is indicated for the occlusion of the heart's left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures.

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, without assistance from a camera, endoscope, etc., or any other viewing technology. This includes procedures performed by sternotomy (full or partial as well as thoracotomy (single or multiple).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. Submitter

Manufacturer: AtriCure, Inc.
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West Chester, OH 45069
P: 513-755-4100
F: 513-755-4108

Contact Person: Brittany Lowe
Regulatory Affairs

Alternate Contact: Jonathan McElwee, RAC
Senior Regulatory Specialist

Date Prepared: 04/14/2015

II. Device

Name of Device: AtriClip™ LAA Exclusion System with preloaded Gillinov-Cosgrove Clip

Common Name: Implantable Clip and Clip Applier

Classification Name: Implantable Clip and Clip Applier (21 CFR 878.4300 and 4800)

Regulatory Class: Class II

Product Code: FZP

III. Predicate Device

The device proposed for modification in this submission is the AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip cleared via 510(k) K093679 on June 10, 2010, K122276 on August 29, 2012, K131107 on May 14, 2013, and K142120 on August 28, 2014.

The predicate devices have not been subject to a design-related recall.

No reference devices were used in this submission.

IV. Device Description

The AtriClip LAA Exclusion System consists of a single use, sterile, self-closing, implantable Clip preloaded on a Single Use Clip Applier. When closed, the Clip applies uniform pressure over the length of the Clip to ensure consistent, reproducible, and secure occlusion of the left atrial appendage (LAA). The Clip is available in the following lengths to accommodate different sizes of LAA: 35 mm, 40 mm, 45 mm, and 50 mm.

The Clip Applier is a disposable device with a handle, shaft, suture anchors, and deployment loop which contains the Clip. This Special 510(k) contains manufacturing modifications to the proposed

AtriClip LAA Exclusion System intended to provide AtriCure with an alternate raw material source for the Polyethylene terephthalate (PET) of the knit braid polyester used in the AtriClip implant.

V. Indications For Use

The AtriClip LAA Exclusion System is indicated for the occlusion of the left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures.

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, without assistance from a camera, endoscope, etc., or any other viewing technology. This includes procedures performed by sternotomy (full or partial) as well as thoracotomy (single or multiple).

VI. Comparison Of Technological Characteristics With The Predicate Device

- The devices have the same intended use and;
- No changes were made in operating principle, or specifications of performance.
- The results of the verification and validation testing:
    - Demonstrated equivalency in performance
    - Device biocompatibility remains unchanged
    - Did not raise any new issues of safety
- No changes were made to the labeling.
- No changes were required in packaging sterilization or expiration dating.

VII. Performance Data

Chemical characterization and *in vitro* biocompatibility screening testing was conducted to demonstrate equivalence of the knit braided polyester sourced from the various suppliers of PET raw material.

VIII. Conclusions

The modified AtriClip LAA Exclusion System is equivalent to the previously cleared AtriClip LAA Exclusion System as there is no change to intended use or the basic design of the Clip.